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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/081,010

02/15/2002

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05/17/2006

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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|-----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/081,010 | MARGARON ET AL. | |
| | Examiner | Art Unit | |
| | Zohreh A. Fay | 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Claims 1-41 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing or treating inflammation, does not reasonably provide enablement for preventing inflammation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method for reducing or preventing inflammation arising from normal does photodynamic therapy using a low dose light.

2) The state of the prior art:

The prior art does not recognize that prevention of inflammation is easily accomplished. According to *Lance Current Medical Diagnosis & Treatment* 43rd Edition, page 157, the treatment of uveitis, which is an inflammatory eye disorder, is done by the use of steroids and antibiotics. There is no teaching of the prevention method for such disorder.

3) The relative skill of those in the art:

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The relative skill of those in the art is high.

4) The predictability or unpredictability of the art:

The unpredictability of pharmaceutical and chemical art is high.

5) The breath of the claims:

The claims are very broad and encompass reduction and prevention of inflammation arising from normal dose photodynamic therapy.

6) The amount of direction or guidance provided:

Applicant's specification provides guidance for and it is only enabled for reduction of inflammation arising from photodynamic therapy.

7) The presence or absence of working examples;

There are no examples in the specification to demonstrate the effect of low dose light in preventing the inflammation caused by normal dose photodynamic therapy.

8) The quantity of experimentation necessary;

Since preventing inflammation arising from photodynamic therapy should be determined by painstaking experimentation, one of ordinary skill in the art would be burdened with undue experimentation to determine if low dose light would prevent the inflammation arising from normal dose photodynamic therapy.

Claims 1-26 and 29-⁴¹~~32~~ are rejected under 35 U.S.C. 103 (a) as being unpatentable Over WO Patent 98/34644 for the reasons set forth on pages 2 and 3 of the office action of September 21, 2005.

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Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant alleges criticality to the steps of the claimed invention in comparison with the prior art of record. Applicant also alleges criticality to the low dose light or PDT of the claimed invention in comparison with the dosages used by the prior art. The allegations are not well taken. The prior art teaches the concept of exposing a damaged tissue to a low dose photosensitizing agent or low dose light in order to reduce inflammation associated with photodynamic therapy. The prior art also teaches that normal dose photodynamic therapy can cause inflammation. See page 17, lines 3 and 4, page 35 lines 24-29 and page 36 lines 1-15. Thus, the concept of treating or reducing inflammation caused by photodynamic therapy by modifying the light or the concentrations of PDT is taught by the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

ZOHREH FAY
PRIMARY EXAMINER
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